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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,009	01/25/2006	Dirk Muhlhoff	3081.144WOUS	9949

24113 7590 09/18/2009
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EXAMINER

HUNTER, RONALD A

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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09/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,009	Applicant(s) MUHLHOFF ET AL.	
	Examiner RONALD HUNTER	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 29, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to **claims 20-31** have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 4/29/2009 have been fully considered but they are not persuasive. The amended **claim 32** as recited "which is parallel to a direction in which the laser radiation is applied" is based on intended use and therefore does not further limit the claim. Subsequently, the **claims 33-46** have not been amended to overcome the prior art and are fully taught by Swinger et al. in view of Gerlach et al.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In claim 32, line 1 - applicant positively recites part of a human, i.e. "a transparent material (cornea)". Thus claims 32-46 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 – It is unclear what, if any structure is intended to be implied by the recitation “which is parallel to a direction in which the laser radiation is applied.” For purposes of examination, examiner has interpreted the recitation as providing no further limiting structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22, 24, & 26 are rejected under 35 U.S.C. 102(b) as being anticipated by **Juhasz et al. (US 5,993,438 A)**.

Regarding claims 20-22, Juhasz et al. disclose a method for performing photodisruption and removal of tissue in a stroma in a cornea of an eye using a pulsed laser beam, which is sequentially focused to individual spots at a plurality of points in the stroma (*column 1, lines 63-67*). Examiner has interpreted a pattern of spots in each layer positioned in a spiral (*substantially elliptical/circular*) pattern as, *shifting a focal point at a maximum speed which is lower in a first spatial direction and substantially perpendicular to the two other spatial directions, guiding the focal point such that it follows contour lines located in the first and second special directions*, and which is substantially centro-symmetric to the optical axis of the eye (*parallel to an axis along which the application of laser radiation is made*). The result is a plurality of substantially flat layers of photodisrupted stromal tissue, each layer being substantially perpendicular and substantially symmetric to the optical axis (*Fig. 2; column 3, lines 29-34*).

Regarding claim 24, Juhasz et al. disclose a separation of spot distances between focal spot central points on a path must be established so that the tissue removal along the path will be substantially continuous (*Fig. 5; column 6, lines 43-46*).

Regarding claim 26, Juhasz et al. disclose a pattern of spots in each layer positioned in a spiral pattern (*contour lines*). Examiner has interpreted the tissue photodisruption along layers **60, 58, 56, 54 & 52** as *moving the focal point for each contour line except for a residual portion of the contour line and making a transition to the next contour line in the residual portion by shifting the focal point in the first spatial direction* (*Fig. 2; column 3, lines 29-34*).

Claims 32-43 & 46 are rejected under 35 U.S.C. 102(b) as being unpatentable by **Swinger et al. (6,325,792 B1)**.

Regarding claims 32, 33, 40-42, Swinger et al. disclose an apparatus for corneal surgery (*column 1, lines 15-17*). A lasing medium of the pulsed laser apparatus uses lasing ions such as titanium, chromium or neodymium (for example, $Ti_3 : Al_2O_3$, $Cr:LiSrAlF_6$, $Nd:YLF$, or similar lasers) (*column 36, lines 53-56*), the laser unit **100** includes a seed laser **102** and a scanner-amplifier laser **104** (*column 17, lines 16-17*), and the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot **58** is then moved in a spiral (*Fig. 7, # 619*) scanning motion under computer control (*column 25, lines 12-14*). The ablation proceeds from posterior to anterior within the cornea to avoid absorption of the beam energy by plasma. Thus, the beam spot is always moving into unablated tissue (*substantially along the contour line except for a residual portion then shifting in the first spatial direction to the next contour line*) (*column 30, lines 60-63*), wherein examiner has interpreted the ability to produce a curved surface substantiates the use of adjustable optics in a spatial direction which is parallel to a direction in which the laser radiation is applied. Examiner has also interpreted the computer controlled spiral scanning motion corrects higher orders of curvature according to contour lines in planes perpendicular to the first spatial direction without using higher orders of curvature.

Regarding claim 34, Swinger et al. disclose adjustable optics with a telescope arrangement comprising a zoom lens **106** and mirrors **122, 126, & 134** as **seen in figure 6**.

Regarding claim 35, Swinger et al. disclose the scanning unit comprises two tilting mirrors with crossed axes for rotation to affect the focus shift in the two other spatial directions (*view Fig. 6: 122, 126, 116 & 134*).

Regarding claims 36 & 37, Swinger et al. disclose excisions illustrated in **FIG. 7** include a straight channel **603**, a curved channel **605**, a point **607**, a line **609**, and interrupted line **611**, a curve of varying depth **613**, a circular area **615**, a square or parallelepiped area **617**, or a spiral **619**. This invention encompasses any combination of such excisions, *wherein an ellipticity of 1.0 is a circle*.

Regarding claims 38 & 39, Swinger et al. disclose an ablation zone edge **224**, surrounded by a plate of annular shape **226** with width **228** and by directing the surgical laser beam **S** to make a pair of opposing curved excisions **906** along an axis **908** relatively to the center of the eye, the refractive power of the eye is decreased along the axis. The exact length **d** and the location of the excision can vary according to the amount of desired correction, in known fashion (*column 21, lines 13-19*), the beam intensity controller **112** is coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam **S** as required for a particular surgical procedure (*Fig. 6; column 17, lines 50-53*) and spot **58** is then moved in a scanning motion under computer control, along the line **56**, which in fact represents the area of ablation of diameter **D6** (*Fig. 15C; column 25, lines 12-14*).

Regarding claim 43, Swinger et al. disclose placing an applanator plate (*contact glass*) (Fig. 14A, #11) in contact with the cornea of a patients eye to teach placing a contact glass onto the material, said contact glass imparting a particular shape to the material, and considering said shape for the contour lines (*column 23, line 43-45 & column 24, lines 36-44*).

Regarding claim 46, Swinger et al. disclose upon command of the computer control unit **114**, or failure of the entire system, electrical energy to the solenoid is cut off, causing the solenoid to retract the shield into position to block the path of the surgical laser beam **S** (*attenuation*) (Fig. 6, column 18, lines 16-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 30 & 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Juhasz et al. (US 5,993,438 A)**.

Regarding claim 25, Juhasz et al. fail to teach average distances between adjacent contour lines are maintained constant within a tolerance of plus or minus about ten percent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Juhasz's et al. invention by maintaining an average distance tolerance of plus or minus ten percent to improve accuracy, wherein it is well known in the art that precision is an extremely important factor in successful ophthalmic laser surgery.

Regarding claim 30, Juhasz et al. fail to teach deactivating the laser radiation with respect to generating optical breakthroughs when the contour line extends outside a desired region of the material in which the cut is to be produced.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Juhasz's et al. invention by deactivating the laser, wherein deactivation of the laser when a breach beyond a target area occurs is considered an appropriate and commonly known response to prevent damage to peripheral tissue during ophthalmic surgery.

Regarding claim 31, Juhasz et al. disclose a pattern of spots in each layer positioned in a spiral (*substantially elliptical/circular*) pattern (*Fig. 2; column 3, lines 29-34*).

Claims 44 & 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Swinger et al. (US 6,325,792 B1)**.

Regarding claim 44, Swinger et al. disclose upon command of the computer control unit **114**, or failure of the entire system, electrical energy to the

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solenoid is cut off, causing the solenoid to retract the shield into position to block the path of the surgical laser beam **S** (*attenuation*) (*Fig. 6, column 18, lines 16-20*).

But, Swinger et al. fail to teach deactivation of the laser radiation.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Swinger's invention by deactivating the laser, wherein deactivation of the laser when a breach beyond a target area occurs is considered an appropriate and commonly known response to prevent damage to peripheral tissue during ophthalmic surgery. Furthermore, applicant has not established an advantage over deactivation vs. attenuation the laser radiation.

Regarding claim 45, Swinger et al. disclose excisions illustrated in **FIG. 7** include a straight channel **603**, a curved channel **605**, a point **607**, a line **609**, and interrupted line **611**, a curve of varying depth **613**, a circular area **615**, a square or parallelepiped area **617**, or a spiral **619**. This invention encompasses any combination of such excisions.

Claim 23 & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Juhasz et al. (US 5,993,438 A)** in view of **Swinger et al. (US 6,325,792 B1)**.

Regarding claim 23, Juhasz et al. fail to teach the substantially elliptical contour lines have an ellipticity of between about 1.0 and 1.2.

However, Swinger et al. disclose excisions illustrated in **FIG. 7** include a straight channel **603**, a curved channel **605**, a point **607**, a line **609**, and interrupted line **611**, a curve of varying depth **613**, a circular area **615**, a square or parallelepiped area **617**, or

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a spiral **619**. This invention encompasses any combination of such excisions, *wherein an ellipticity of 1.0 is a circle*.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Juhasz's et al. invention with the circular area as taught by Swinger to insure precision of ophthalmic laser surgery along two spatial direction on the cornea.

Regarding claim 29, Juhasz et al. fail to teach placing a contact glass onto the material, said contact glass imparting a particular shape to the material, and considering said shape for the contour lines.

However, Swinger et al. teach placing an applanator plate (*contact glass*) (*Fig. 14A, #11*) in contact with the cornea of a patients eye to teach placing a contact glass onto the material, said contact glass imparting a particular shape to the material, and considering said shape for the contour lines (*column 23, line 43-45 & column 24, lines 36-44*).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Juhasz's et al. invention with an applanator plate as taught by Swinger et al. to improve corrective efficiency of the ophthalmic laser surgery method.

Claims 27 & 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Juhasz et al. (US 5,993,438 A)** in view of **Bille (US 7,101,364 B2)**.

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Regarding claims 27 & 28, Juhasz et al. disclose a method for performing photodisruption and removal of tissue in a stroma in a cornea of an eye using a pulsed laser beam, which is sequentially focused to individual spots at a plurality of points in the stroma (*column 1, lines 63-67*) and pattern of spots in each layer positioned in a spiral pattern (*contour lines*) which is substantially centro-symmetric to the optical axis of the eye. The result is a plurality of substantially flat layers (*without higher orders of curvature*) of photodisrupted stromal tissue (*sectioned curved cut surface*), each layer being substantially perpendicular and substantially symmetric to the optical axis (*Fig. 2; column 3, lines 29-34*).

But, Juhasz et al. fail to teach obtaining the contour lines for higher orders of curvature, which is corrected with regard to higher orders of curvature.

However, Bille teaches an exemplary spiral scanning pattern that can be used to minimize heat damage to non-target tissue during photoablation of target tissue (*Fig. 4; column 6, lines 58-60*) and correction for a higher order aberration (*column 10, line 5*).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Juhasz's et al. invention with the higher order curvature correction as taught by Bille to improve versatility of and corrective accuracy of the ophthalmic laser surgery method.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUNTER whose telephone number is (571)270-7133. The examiner can normally be reached on Monday - Friday, 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUNTER/
Examiner, Art Unit 3769

/david shay/
Primary Examiner, Art Unit 3769